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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,409	01/18/2002	Chu-Wen Yang	12005-003001	9623

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225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,409

Applicant(s)

YANG ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Claims 1-28 are pending in the application and are currently subject to restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-5, drawn to a polypeptide, classified in class 530, subclass 350.

Group II. Claims 6-10 and 16-18, drawn to a nucleic acid molecule and a method for producing a transcript in a cell, classified in class 536, subclass 24.5 and class 435, subclass 69.1.

Group III. Claims 11-15, drawn to an antibody, classified in class 530, subclass 387.9.

Group IV. Claims 19-23, drawn to a method for determining whether a patient has a cell proliferation disorder, classified in class 435, subclass 6.

Group V. Claims 24-28, drawn to a method for identifying a candidate compound useful for treating a cell proliferation disorder, classified in class 435, subclass 6.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-III are patentably distinct products.

The inventions of Groups I-III are patentably distinct, each from the other, because the inventions of Group I are polypeptides, the inventions of Group II are nucleic acid molecules, and the inventions of Group III are antibodies.

Polypeptides and polynucleotides are chemically distinct products, since polypeptides are composed of polymers of amino acids, whereas polynucleotides are composed of polymers of nucleotides. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, a polypeptide can be produced by means, other than the recombinant means by which a polynucleotide encoding a polypeptide might be used to produce the polypeptide, since a polypeptide can be produced by biochemical means, including, for example, affinity chromatography. In addition, while the polynucleotide might encode the polypeptide, generally, it can also encode another polypeptide using the information provided by an alternative open reading frame; and furthermore, since a polynucleotide can be used as a probe in hybridization-based analyses, the information provided by a polynucleotide can be used to isolate different polynucleotides encoding polypeptides, which have amino acid sequences that differ from the amino acid sequence encoded by the disclosed polynucleotide. Consequently, the disclosed relationship between a polynucleotide capable of encoding a polypeptide and the polypeptide is not exclusive, since either the claimed polynucleotide or the claimed polypeptide can also be related to other polynucleotides or polypeptides, which are materially and chemically different from the claimed inventions. Therefore, the inventions of Group I and II are patentably distinct products.

The inventions of Groups I and II have acquired a separate status in the art, as evidenced by their different classifications, and the search performed in examining claims drawn to a polynucleotide is a different from the search performed in examining claims drawn to a polypeptide. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of Group I would not suffice to provide adequate information regarding the merit of the claims of Group II, and vice versa, since

the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups I and II, an examination of both would constitute a serious burden. Moreover, because the disclosed relationship between the polynucleotide and the polypeptide encoded by the polynucleotide is not absolute or exclusive of other relationships with different polynucleotides or polypeptides, the search of either group will likely provide information that is relevant to one but not the other; and as such, searching one in addition to the other would be unduly burdensome.

Since the inventions of Groups I and II are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Group I and the invention of Group III are patentably distinct because, although both are polypeptides, the invention of Group I is a cell cycle regulating protein, whereas the invention of Group III is an antibody. An antibody, such as an immunoglobulin G (IgG) molecule, typically comprises four polypeptides: two light chains and two heavy chains, each containing constant and variable regions, which interact with one another to form an antigen-binding domain comprised of amino acid residues in each chain. In contrast, the cell cycle regulating protein is disclosed as consisting of a single polypeptide chain; so the inventions of Groups I and III are structurally distinct from one another. Thus, any relationship between an antibody and a polypeptide to which the antibody binds is codependent upon the structural (i.e., antigenic) information provided by the polypeptide, which is recognized as the antigenic determinant to which the antibody binds, and the selective binding nature of the antigen-binding domain of the antibody. However, a polypeptide comprises multiple antigenic determinants and can thus elicit the production of multiple different antibodies, which recognize and bind structurally distinct portions (i.e., epitopes) of the polypeptide. Furthermore, an antibody is capable of recognizing and binding antigenic determinants that are shared by polypeptides, which are otherwise structurally and/or functionally distinct from the claimed polypeptide to which it binds (e.g., a human protein's mouse homolog, or a different member of a functionally related family of proteins).

Consequently, the disclosed relationship between an antibody that binds a polypeptide and the polypeptide is not exclusive, since either the claimed antibody or the claimed polypeptide can also be related to other polypeptides or antibodies, respectively, which are materially and chemically different from the claimed inventions. Therefore, the inventions of Group I and III are patentably distinct products.

Searching both the invention of Group I and the invention of Group III would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. A search of relevant sequence databases using the entire amino acid sequence of the polypeptide as query is necessary for the determination of the novelty and unobviousness of the polypeptide. However, such a search is not necessary, or sufficient to identify antibodies that bind the polypeptide, since antibodies that bind an epitope of the polypeptide may be known, even if the polypeptide is not (e.g., a anti-phosphotyrosine antibody binds a phosphotyrosine epitope, which is shared by numerous different proteins, and which would bind a novel tyrosine phosphorylated polypeptide). Accordingly, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, having to search both inventions of Groups I and III would constitute a serious burden.

Since the inventions of Groups I and III are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups II and III are patentably distinct because a polynucleotide and an antibody are chemically distinct molecules, since a polynucleotide is composed of polymers of nucleotides, whereas antibodies are composed of polymers of amino acids. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino

acid sequence of the polypeptide. However, the claimed polynucleotide does not encode a polypeptide chain of the claimed antibody; and the claimed antibody cannot be encoded by the claimed polynucleotide. Therefore, inventions of Group II and III are patentably distinct products.

Searching both the invention of Group II and the invention of Group III would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. Therefore, having to search both inventions of Groups II and III would constitute a serious burden.

Since the inventions of Groups II and III are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

Inventions IV and V are patentably unrelated methods.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 806.04 and 808.01. The instant specification does not disclose that the inventions of IV and V are useable together. The claimed method for determining whether a patient has a cell proliferation disorder (the invention of Group IV) and the claimed method for identifying a candidate compound useful for treating a cell proliferation disorder (the invention of Group V) are unrelated because they are materially different, as each utilizes different products, and comprise distinct process steps; accordingly, each method has a different mode of operation. The purpose or objective of the two inventions is different, since the intended purpose of the invention of Group IV is to diagnose a cell proliferation disorder, whereas the intended purpose of the invention of Group V is to identify a potentially useful therapeutic compound.

Searching both the invention of Group IV and the invention of Group V would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their art-recognized divergence in objectives and modes of

operation. Moreover, because the necessary searches are not the same, nor are they coextensive in nature and scope with one another, having to search both inventions of Groups IV and V would constitute a serious burden.

Since the inventions of Groups II and III are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups I-III and the inventions of Groups IV and V are unrelated because the products of Group I, II, or III are not specifically used or otherwise involved in the processes of Groups IV or V.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

Claims 1-30 are drawn to patentably distinct species of inventions, wherein the polypeptide comprises SEQ ID NO: 2 encoded by SEQ ID NO: 1 or SEQ ID NO: 4 encoded by SEQ ID NO: 3, or wherein the nucleic acid or polynucleotide sequence is SEQ ID NO: 1 or SEQ ID NO: 3.

The polypeptides of SEQ ID NO: 2 and SEQ ID NO: 4 are patentably distinct, because SEQ ID NO: 2 is the amino acid sequence of a putative protein encoded by a complementary DNA (cDNA) molecule isolated from human cells, whereas SEQ ID NO: 4 is the amino acid sequence of a putative protein encoded by a cDNA molecule isolated from mouse cells. Moreover, the amino acid sequences of SEQ ID NO: 2 and

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SEQ ID NO: 4 are different; therefore, a different search is required to consider claims drawn to one or the other, which is not the same, or coextensive with the search that is necessary to consider the other. Furthermore, the polynucleotide sequences of SEQ ID NO: 1 and SEQ ID NO: 3 are different; therefore, a different search is required to consider claims drawn to one or the other, which is not the same, or coextensive with the search that is necessary to consider the other.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant must do so by specifically identifying the amino acid sequence (i.e., SEQ ID NO: 2 or SEQ ID NO: 4) or polynucleotide sequence (i.e., SEQ ID NO: 1 or SEQ ID NO: 3) to which the claims of the elected group of inventions are to be drawn during prosecution on the merits.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

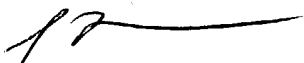
7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
October 1, 2004